TAB

ARMY review(s) completed.

Approved For Release 2004/07/09 : CIA-RDP96-00788R001500090010-7

DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
ARLINGTON HALL STATION
ARLINGTON, VIRGINIA 22212

REPLY TO ATTENTION OF

IACC

17 July 1984

MEMORANDUM FOR ASSISTANT CHIEF OF STAFF FOR INTELLIGENCE

SUBJECT: INSCOM CENTER LANE Project (U)

1. (U) We have completed a review of project CENTER LANE with a focus on resources involved, results obtained and the role of INSCOM in this area.

2. (S) INSCOM has invested considerable effort over a long period of time to develop the remote viewing technology. As a result the Army enjoys a monopoly on this revolutionary concept for intelligence collection. We must insure that we do not lose this knowledge and experience in any action taken to change INSCOM's role in the use and development of the technology.

3. (S) I am concerned about these three aspects of the program.

a. Continued research and development. We cannot abandon the work already done if for no other reason than to keep pace with the effort being expended by our adversaries.

b. Current operations. Intelligence users in the Army, DIA, NSA and CIA have all tasked this methodology to augment established disciplines and for missions that would be extremely difficult or impractical for any other collection resource. The Intelligence Community cannot afford the loss of this capability while it waits for a total refinement and understanding of the observed phenomenon.

c. People involved. Changing INSCOM's role affects the dedicated personnel involved. We must insure the timely and fair reassignment of our excellent cadre who may or may not wish or be able to participate in some further continuation of the program.

4. (S) In spite of these concerns it is my opinion that INSCOM, who has supported this project with S and IA funds and personnel assigned without spaces, should discontinue our involvement with psychoenergetic research and operations. To mitigate adverse impact in the areas of concern expressed above I intend to cease INSCOM CENTER LANE Project operations on 30 Sept 1984, but allow completion of outstanding contracts and training by 31 December 1984. This would:

WARNING NOTICE: CENTER LANE SPECIAL ACCESS PROGRAM RESTRICT DISSEMINATION TO THOSE WITH VERIFIED ACCESS TO CATEGORY THREE(3)

CLASSIFIED BY: CDR, INSCOM
DECLASSIFY ON: OADR

SENSITIVE INTELLIGENCE SOURCES AND METHODS INVOLVED NOT RELEASABLE TO FOREIGN NATIONALS

COPY 3 OF 3 COPIES

IACG
SUBJECT: INSCOM CENTER LANE Project(U)

17 July 1984

a. (U) Allow the reassignment of ICLP personnel on an equitable basis.

b. (S/CL-3/NOFORN) Permit trainees to complete training and become 60% operational.

c. (S/CL-3/NOFORN) Permit timely and undisrupted transfer of (1) ICLP operations to a national agency such as DIA or NSA and (2) ICLP phenomena validation and technology extension to the US Army Medical Research and Development Command.

d. (U) Permit preparation of comprehensive after action reports, thereby preserving vital institutional knowledge and technical details that would otherwise be permanently lost.

5. (U) Accordingly, I request that:

a. OACSI coordinate this action to insure that there is no objection at Department of Army.

b. INSCOM be authorized to coordinate directly with DIA, NSA and Medical R&D Command with regard to para. 4c.

HARRY E. SOYSTER
Brigadier General, USA
Commanding

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Approved For Release 2004/07/09 : CIA-RDP96-00788R001500090010-7

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT CHIEF OF STAFF FOR INTELLIGENCE
WASHINGTON, DC 20310

REPLY TO ATTENTION OF

DAMI-ISH

1 AUG 1984

MEMORANDUM THRU VICE CHIEF OF STAFF, ARMY
ARMY GENERAL COUNSEL 22 Aug 1984

FOR SECRETARY OF THE ARMY

SUBJECT: CENTER LANE (U)--ACTION MEMORANDUM

Approved 8/23/84

1. (S/CL-1/NOFORN) Purpose: To obtain your approval for the discontinuation of Intelligence and Security Command (INSCOM) involvement with psychoenergetic research and operations.

2. (U) Discussion:

a. (S/CL-1/NOFORN) CENTER LANE is an INSCOM Special Access Program which utilizes an aspect of parapsychology known as Remote Viewing (RV) as the collection method for obtaining information of intelligence interest. Your approval for the Army to engage in CENTER LANE activities was most recently obtained on 1 Sep 83.

b. (S/CL-1/NOFORN) CDR INSCOM has reviewed the project and reached the decision to discontinue the command's involvement with psychoenergetic research and operations. Recognizing that INSCOM has invested considerable effort over a long period of time to develop the RV technology and holds a monopoly on this revolutionary concept for intelligence collection, he desires that we not lose this knowledge and experience.

c. (U) As such, INSCOM intends to do the following:

(1) (S/CL-1/NOFORN) Cease CENTER LANE operations on 30 Sep 84, but allow contracts and training to continue to 31 Dec 84.

(2) (S/CL-3/NOFORN) Transfer project operational aspects to DIA and technology extension to the US Army Medical Research and Development Command. In the event DIA is not interested in the transfer, NSA will be considered.

CENTER LANE

CLASSIFIED BY CG INSCOM
DECLASSIFY ON OADR

CLOSE HOLD/HANDCARRY

SECRET

1 AUG 1984

DAMI-ISH
SUBJECT: CENTER LANE (U)--ACTION MEMORANDUM

d. (S/CL-1/NOFORN) It is anticipated that discussion between INSCOM and the above organizations will result in a Memorandum of Agreement transfering all CENTER LANE activity outside of INSCOM, while insuring that research and operational capabilities are protected and the people involved are reassigned on an equitable basis.

3. (S/CL-1/NOFORN) Recommendation: That the Secretary of the Army approve the INSCOM concept for discontinuing involvement with psychoenergetic research and operations and transferring CENTER LANE functions.

JAMES H. SHUFELT
Brigadier General, USA
Acting ACofS for Intelligence

LTC Fox/50114
Typed by C. Huggins

29 AUG 1984
APPROVED BY
SECRETARY OF THE ARMY

CHARLES E. DOMINY
COL, GS
EXECUTIVE TO THE
SECRETARY OF THE ARMY

SECRET

NOT RELEASABLE TO FOREIGN NATIONALS

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Approved For Release 2004/07/09 : CIA-RDP96-00788R001500090010-7

CENTER LANE

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT CHIEF OF STAFF FOR INTELLIGENCE
WASHINGTON, DC 20310

REPLY TO
ATTENTION OF

DAMI-ISH

10 SEP 1984

SUBJECT: INSCOM CENTER LANE Project (U)

Commander
USA Intelligence and Security Command
Arlington Hall Station
Arlington, VA 22211

1. (U) Reference memorandum, INSCOM, IACG, 17 Jul 84, subject: INSCOM CENTER LANE Project (U), (S/CL-3/NOFORN).

2. (S/CL-1/NOFORN) The Secretary of the Army has approved ending the Intelligence and Security Command's (INSCOM) involvement with psychoenergetic research and operations. A copy of the OACSI, DA memorandum to the Secretary on the subject, with his noted approval, is enclosed.

3. (S/CL-3/NOFORN) You are authorized to coordinate directly with CIA, DIA, NSA, and the Army Medical R&D Command regarding transfer of CENTER LANE operations and research. Any transfer of project personnel, files, equipment, contracts, etc, should be covered by a Memorandum of Agreement (MOA). Any such MOA should be provided for review by the ACSI prior to implementation.

4. (S/CL-1/NOFORN) The CENTER LANE Special Access Program (SAP) should be terminated or transferred, as appropriate, once INSCOM involvement is discontinued.

a. (S/CL-3/NOFORN) If the Medical R&D Command becomes involved and desires SAP protection, the project name should be changed and the Secretary of the Army duly notified.

b. (S/CL-2/NOFORN) If a non-Army agency assumes the project functions, the SAP should be terminated. If that agency desires SAP protection and support for an interim period this should be provided under a new name.

1 Encl
as

JAMES W. SHUFELT
Brigadier General, USA
Acting ACofS for Intelligence

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DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT CHIEF OF STAFF FOR INTELLIGENCE
WASHINGTON, DC 20310

REPLY TO ATTENTION OF

DAMI-ISH

4 OCT 1984

SUBJECT: Memorandum of Agreement (U)

Commander
USA Intelligence and Security Command
Arlington Hall Station
Arlington, VA 22212

1. (S/CL-2/NOFORN) Reference memorandum, INSCOM, IAGC, 26 Sep 84, subject: Memorandum of Agreement, Transfer of INSCOM CENTER LANE Project (ICLP) to DIA (S/CL-2/NOFORN).

2. (U) Reference proposed Memorandum of Agreement (MOA) is approved.

3. (S/CL-2/NOFORN) Request you consider the inclusion of some detail on the procedure to be followed in transferring personnel to DIA. INSCOM may detail the indivíduals involved for up to one year to allow time for DIA to identify spaces. Once such spaces are available, the detailed personnel may be given a Permanent Change of Station. If DIA desires a change in authorized strength to allow for immediate PCS reassignment, they may apply for it through JCS. OACSI, DA will support such a change in status if the subject becomes an issue.

WILLIAM E. ODOM
Lieutenant General, USA
ACofS for Intelligence

Classified by Cdr, INSCOM
Declassify on: OADR

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US ARMY
INTELLIGENCE AND SECURITY COMMAND
CENTER LANE TRAINING AND APPLICATIONS PROCEDURES

WARNING NOTICE: CENTER LANE SPECIAL ACCESS PROGRAM
RESTRICT DISSEMINATION TO THOSE WITH VERIFIED ACCESS
TO CATEGORY THREE (3)

SENSITIVE INTELLIGENCE SOURCES AND METHODS INVOLVED
NOT RELEASABLE TO FOREIGN NATIONALS

CLASSIFIED BY: CDR, INSCOM

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US ARMY
INTELLIGENCE AND SECURITY COMMAND
CENTER LANE TRAINING AND APPLICATIONS PROCEDURES

INDEX

IAGAP-F-SD

6 June 1984

US ARMY
INTELLIGENCE AND SECURITY COMMAND
CENTER LANE TRAINING AND APPLICATIONS PROCEDURES

1. (S/CL-1/NOFORN) GENERAL: The procedures set forth herein detail the activities of the US Army Intelligence and Security Command (INSCOM) Special Access Program (SAP) CENTER LANE in psychoenergetics. These procedures are in effect for the period required to train and apply psychoenergetics. They are effective and do not involve any practices which expose participants to harmful circumstances or substances such as drugs.

2. (S/CL-2/NOFORN) DEFINITIONS:

a. (U) Psychoenergetics: A mental process by which an individual perceives, communicates with, and/or perturbs characteristics of a designated target, person, or event remote in space and/or time from that individual. It does not involve any electronic devices located or focused at the target, nor does it involve classical photo interpretation of photographs obtained from overhead or oblique means.

b. (U) Psychoenergetic Source: A person who perceives, communicates with, and/or perturbs characteristics of a designated target, person, or event.

c. (U) Psychoenergetic Trainee: A person being trained to be a psychoenergetic source.

d. (U) Psychoenergetic Session: A single attempt by a psychoenergetic source and an interviewer/monitor to perceive, communicate with, and/or perturb characteristics of a designated target, person, or event.

e. (U) Interviewer/Monitor: The individual who interacts directly with the psychoenergetic source before, during, and after the session.

WARNING NOTICE: CENTER LANE SPECIAL ACCESS PROGRAM
RESTRICT DISSEMINATION TO THOSE WITH VERIFIED ACCESS
TO CATEGORY THREE (3)

SENSITIVE INTELLIGENCE SOURCES AND METHODS INVOLVED
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f. (U) Remote Viewing: The name of a method of psychoenergetic perception. A term coined by SRI-International (SRI-I) and defined as "the acquisition and description, by mental means, of information blocked from ordinary perception by distance, shielding, or time."

g. (U) Coordinate Remote Viewing (CRV): A Remote Viewing technique that requires the use of coordinates as targeting information.

h. (U) Targeting Information: An abstract referent which represents the target of interest.

i. (U) Target/Site: A specific area, person or event at a specific time.

j. (U) Discrete State: A type of psychoenergetic activity in which the source perceives his consciousness to be located at the target.

3. (S/CL-2/NOFORN) MILITARY OBJECTIVE: It is the objective of these procedures to maintain the quality of psychoenergetic training and applications so that CENTER LANE will continue to support the broad spectrum of intelligence and counterintelligence requirements in collection, target acquisition, and deception.

4. (S/CL-3/NOFORN) MILITARY APPLICATIONS: CENTER LANE applications of psychoenergetics include but are not limited to: (1) targeting of key enemy military personnel from covert agents to key battle commanders, (2) monitoring hostile military movements, lines of communication, and specific technologies, (3) detecting changes in the state of military units, (4) detecting and assessing hostile intelligence efforts targeted against friendly units/missions, and (5) detecting and assessing hostile technological capabilities in specific locations. Since US Army personnel, units, materiel, and operations are subject to a similar hostile intelligence service threat, CENTER LANE can assist in devising countermeasures to eliminate or reduce vulnerabilities.

5. (S/CL-2/NOFORN) APPROVAL HISTORY:

a. (S/CL-2/NOFORN) Concept Approval: The Commander, US Army Materiel Development and Readiness Command (DARCOM) approved in principle the US Army Material Systems Analysis Activity (AMSAA) involvement in the project GRILL FLAME; which began in April 1978 (GRILL FLAME was the predecessor to the CENTER LANE Project). In May 1978, the Assistant Chief of Staff for Intelligence (ACSI) accepted lead responsibility for GRILL FLAME applications. Effective 14 January 1981, by approval of

the Under Secretary of the Army, INSCOM became the only active operational GRILL FLAME element in the Army. Program management for GRILL FLAME was transferred to Commander, INSCOM effective 11 February 1981. OACSI, DAMI-ISH remained the Army focal point for policy matters and interface at the national level. Overall DoD responsibility resided with the Defense Intelligence Agency (DIA). Also in 1981, a joint services GRILL FLAME Committee consisting of DIA, the US Air Force and US Army was formed. Later the Air Force Chief of Staff directed that the Air Force withdraw from the committee and all psychoenergetic programs. A comprehensive program was designed to determine the operational parameters and usefulness of psychoenergetics and assess the threat these phenomena posed to national security. At that time DIA was R&D oriented and INSCOM's GRILL FLAME Project was applications oriented. In the FY83 DoD budget review the Budget Subcommittee of the Senate Select Committee on Intelligence curtailed all psychoenergetic activities funded by the Army in the National Foreign Intelligence Program (NFIP), but directed that DIA could complete the third year of their effort and that all future Army funding be budgeted outside the NFIP. INSCOM terminated formal involvement with GRILL FLAME at the end of FY 82; in the fall of 1982, in keeping with congressional desires, the Commanding General INSCOM provided funding from Security and Investigative Activities (S&IA) monies, and continued its efforts under a provisional compartmented SAP nicknamed CENTER LANE. On 1 September 1983, the Secretary of the Army approved continued Army participation in CENTER LANE activities within INSCOM and with appropriate contractors in a cooperative effort with DIA.

b. (S/CL-2/NOFORN) Human Use Approval: GRILL FLAME was designated a "Human Use" program as the result of an Army General Counsel decision in February 1979, which determined that the Project involved "Experimentation on Human Subjects," and that relevant Human Use protocols did indeed apply to Project procedures and technologies. Conduct of the Project under Human Use regulations was first approved in April 1980 by the Under Secretary of the Army. Appendix A contains an historical summary of the Human Use issue, as well as a list of the pertinent regulations, which govern CENTER LANE activities.

6. (S/CL-3/NOFORN) SELECTION OF PERSONNEL:

a. (S/CL-3/NOFORN) Current Selection Criteria: After over a year of participation within the psychoenergetic project, source personnel were tested by the INSCOM Staff Psychologist in an attempt to determine a suitable profile by which further participants could be identified. The specific tests administered were (see Appendix B for test descriptions):

(1) The Minnesota Multiphasic Personality Inventory (MMPI).

(2) Gordon Personal Profile - Inventory (GPI).

(3) Fundamental Interpersonal Relations Orientation-Behavior (FIRO-B).

(4) California Psychological Inventory (CPI).

(5) Edwards Personal Preference Schedule (EPPS).

(6) Personal Orientation Inventory (POI).

For the most part, the group presented itself as emotionally stable with no marked trends. There did appear to be an interesting similarity in defensive style, a tending toward artistic, aesthetic, and cultural interests, and an introversive style of emotional expression. From these test results the INSCOM Staff Psychologist constructed a test that may be used as an initial screening tool in the selection of new psychoenergetic participants. This new test is called the INSCOM Factor Questionnaire. This instrument is used to compare individuals with CENTER LANE sources. A high score suggests that individuals have similar characteristics to operational personnel and may be potential candidates for the project. A score of 20 or higher is considered to be similar to CENTER LANE personnel. Individuals who score within the parameters specified by the INSCOM psychologist would then receive personal interviews with CENTER LANE Project personnel. From these interviews new project participants would be selected and trained.

b. (S/CL-3/NOFORN) Projected Selection Criteria: SRI-I has been contracted to investigate and report on a particular aspect of psychoenergetics relating to operational management of personnel; that is, to determine if a personality testing technique can be created which, when applied to a general population, will delineate specific individuals who exhibit a higher degree of talent for psychoenergetic abilities.

c. (S/CL-2/NOFORN) Voluntary Consent: As required under the regulations governing "Human Use" (see para 2., Appendix A), all personnel operate on a strictly voluntary basis, and may withdraw at any time without any form of prejudicial action or consideration directed against them. Further, participants are informed of any known or potential risks that might be inherent in program participation. This is accomplished through the use of a verbal briefing from a knowledgeable CENTER LANE official, and the execution of a personalized Statement of Consent form outlining all pertinent information and considerations. The voluntary consent requirement pertains to individuals assigned to the CENTER LANE Project and contractors/consultants. A sample of the voluntary consent form is attached as Inclosure 5, Appendix A.

7. (S/CL-1/NOFORN) TRAINING PROCEDURES: To provide a framework for the standardizing of the task of psychoenergetic learning, a number of methodologies are being utilized and conducted within the CENTER LANE Project. These are as follows:

a. (S/CL-3/NOFORN) Orientation Testing/Training:

(1) Purpose: To provide new personnel with an introduction to training and applications procedures.

(2) Administered by: CENTER LANE Project personnel and selected contractor and subcontractors.

(3) Location: Fort George G. Meade, Maryland and other designated locations.

(4) Duration: One to six months.

(5) Description of Procedures: Orientation testing/training is developed from the practical application of state-of-the-art psychoenergetic technology drawn from academic institutions, scientific laboratories, and research establishments around the world. It is an eclectic approach, using those methods which have applications potential. Orientation testing is designed to determine if new personnel have aptitudes which would be of operational value and could be developed through training. This orientation testing consists of a series of controlled exercises in psychoenergetic functioning. New personnel may be asked to attempt to perceive, communicate with, and/or perturb characteristics of a designated target, person, or event remote in space and/or time from that individual. Orientation training is composed of practical exercises in Remote Viewing, lectures, literature review, and observation of others. It includes the use of locally significant sites, as well as more remote geographical locations as targets. A target pool consists of a controlled group of sites or targets and their associated targeting information. Prior to the beginning of a training session, a target is randomly selected from this target pool. Information available concerning the target is kept from the trainee until after the session.

(6) Training Session Preliminaries: Before a first training session is scheduled, the person being trained is oriented fully to the procedure to be followed by the monitor. The trainee is instructed that he or she should state only raw perceptions, since experience has shown that specific definitions are quite often wrong while initial raw perception tends to be correct. Personnel being trained are always encouraged to express their feelings and ideas for enhancing all aspects of the psychoenergetics collection process.

(7) Training Session Dynamics: During the 30-60 minutes prior to the agreed-upon time of a training session, the monitor offers some encouragement to the trainee in the same manner that a coach might give a pep talk to his team. During the 15 minutes immediately before the session the trainee and monitor are generally silent. Experience has shown (unpublished data) that this quiet time enhances the training process. The training room is homogeneously-colored, acoustic-tiled, and featureless, with light controlled by a dimmer, so that environmental distractions can be minimized. During the entire process the trainee and monitor function as a team. The monitor provides encouragement with words of reassurance that the task is, in fact, possible. At no time is the session conducted by the trainee in the absence of all other persons. If the trainee does not have any immediate sensory impressions, the monitor applies no pressure. Rather, the monitor reassures the trainee that there is no time limit for the training session. If it appears to the monitor that the impressions are in some way contradictory or inconsistent, the monitor may then attempt clarification by asking questions in order to verify what the trainee first describes. All sessions are tape-recorded, and pen and paper are available for the trainee to sketch his or her perceptions. Experience has shown that some trainees prefer to combine written and oral descriptions, while some prefer to work sequentially. The average training session for orientation is approximately 15 minutes of actual perception. Trainees generally are not permitted to go beyond 30 minutes as this leads to perceptual confusion and eventual loss of the training affect.

(8) Post Session Dynamics: After the training session is over, the trainee and monitor obtain specific information about the target, either in picture descriptive form for remote geographic sites, or--as in the case of local sites--by actually visiting the target site. The trainee and monitor then discuss the session results. The purpose of this post-session activity is to provide the trainee with the satisfaction of knowing how well he or she did while mental perceptions of the targeted site are still fresh in mind.

b. (S/CL-3/NOFORN) CRV Training:

(1) Purpose: To provide trainees with the requisite skills necessary to perform certain psychoenergetic applications.

(2) Administered by: Contractor and subcontractor personnel.

(3) Location: SRI-I Menlo Park, CA; SRI-I New York, NY; SRI-I Washington D.C.; and other mutually agreed locations as required.

(4) Duration: 12 to 18 months.

(5) Description of Procedure: CRV training is a contracted service provided by SRI-I. The training involves lectures on theory coupled with practical exercises and drills. Particularly effective instructional procedures include active participation wherein the trainee interacts with the curriculum materials by responding, practicing, and testing each step of the material to be mastered; information feedback, wherein the trainee finds out with minimal delay whether the response is correct; and individualized instruction, wherein the trainee moves ahead at his or her own rate. The training procedures have been broken down into several stages representing various elements of CRV phenomena. These stages both facilitate training and actually follow the predictable course of increasing perception which builds itself in specific increments and impact. Stages 1 through 3 appertain to general site features, which become increasingly refined as individual competency with Stage 3 techniques develops. Stage 4 involves perception of specific site elements, a good portion of which may not be available to any other intelligence techniques, save for actual penetration of the site. Stage 5 allows the trainee in a sense to reverse the procedure and "interrogate" his perceptions, allowing clarification of various specific or subtle features of the site. Stage 6 permits the construction of 3-dimensional models of major site characteristics, with increasing refinements in detail. Experience and theory extension indicates that additional increments exist beyond Stage 6. Research is underway to develop and define the parameters and potentials of these additional fields.

(6) Session Dynamics: In conducting a CRV session, a remote viewer or trainee and a monitor begin by seating themselves at the opposite ends of a table in a special remote viewing room equipped with paper and pens, a tape recorder, and an overhead TV camera which allows either recording for documentation, or monitoring by individuals outside the room. The room is homogeneously-colored, acoustic-tiled, and featureless, with light controlled by a dimmer, so that environmental distractions can be minimized. The session begins when the monitor provides targeting information, in the form of specific site coordinates, to the trainee. For training purposes the monitor is allowed to know enough about the site to enable him to determine when accurate versus inaccurate information is being provided. The session then proceeds with the monitor repeating the targeting information at appropriate intervals and providing necessary feedback. The feedback procedure was designed to reinforce the trainee's contact with the site but not to assist him by random cuing. The remote viewer generates verbal responses and sketches, until a coherent

response to the overall task requirement emerges. The use of the quick reaction-response procedure has been found useful in minimizing imaginative embellishment.

(7) Post Session Dynamics: After the training session is over, the trainee and monitor obtain specific information about the target. As in the case of orientation training, this is presented in picture descriptive form for remote geographic sites, or in the case of local sites, may involve actually visiting the target site. The trainee and monitor then discuss the session results, again with the purpose of providing the trainee with the satisfaction of knowing how well he or she did while mental perceptions of the targeted site are still fresh.

c. (S/CL-3/NOFORN) Applications Training:

(1) Purpose: To enable advanced trainees to integrate and expand acquired skills for psychoenergetic applications.

(2) Administered by: CENTER LANE Project personnel.

(3) Location: Fort George G. Meade, Maryland.

(4) Duration: Continuous.

(5) Description of Procedure: Procedures for applications training are essentially identical as those previously presented except in the style of target presented. Applications targets are actual targets of military interest, such as US facilities or USSR sites from which data are available or can eventually be obtained. Targets of this type provide a basis for judgements regarding utility, accuracy, calibration, and depth of detail for any given trainee in a real world environment.

d. (S/CL-3/NOFORN) Advanced Individual Training:

(1) Purpose: To provide experienced sources with advanced individual training to meet applications requirements.

(2) Administered by: CENTER LANE Project personnel, and selected contractors and subcontractors.

(3) Location: Fort Meade, Maryland and various contractor locations.

(4) Duration: Continuous.

(5) Description of Procedure: Individualized advanced training programs are developed to meet specific applications needs. Such programs may involve training in biofeedback,

communications skills, perturbation techniques, discrete state, hemi-sync, search, Neuro-linguistic Programming, and alternate target acquisition methods. One program of particular interest is hemi-sync training conducted by the Monroe Institute of Applied Sciences (MIAS), Faber, VA:

> The MIAS hemi-sync techniques are used to teach sources to control highly specialized mental states conducive to psychoenergetic performance. This form of advanced individual training is only used with sources of proven performance and a recognized degree of maturity. Training is accomplished in four essential phases; (1) application of the Monroe "Discovery" series done at Fort Meade to screen personnel and prepare for phase two; (2) Attendance at the MIAS Gateway program for qualified personnel, conducted in a seminar atmosphere; (3) One-on-one training sessions with Robert A. Monroe at MIAS, which are designed to "customize" individual techniques for specific individual needs; (4) use of specially designed hemi-sync environments during applications training done at Fort Meade.

8. (S/CL-2/NOFORN) PSYCHOENERGETIC APPLICATIONS: CENTER LANE sources can be used to perform psychoenergetic applications in support of intelligence and counterintelligence requirements (see paragraph 3, above). The dynamics of applications sessions parallel those of training sessions. The sequence of events consists of the following: (1) tasking; (2) development of a collection plan; (3) conduct of psychoenergetic session(s); (4) reporting; (5) evaluation. Applications sessions are always conducted under the control and management of CENTER LANE personnel. Sessions may be conducted at Fort Meade or other locations as deemed necessary. Psychoenergetic consultants/contractors may be employed when required to meet applications requirements.

9. (S/CL-3/NOFORN) ADDITIONAL COMMENTS:

a. Selected personnel may use the hemi-sync environment in conjunction with psychoenergetic applications/training.

b. Sources and trainees may be monitored using appropriate non-intrusive biological monitoring equipment.

c. The maximum number of applications sessions for each source will not exceed ten per week.

d. The maximum number of training sessions for each source will not exceed 20 per week.

e. CENTER LANE procedures do not involve the use of drugs, substances, or circumstances harmful to participants. The INSCOM Staff Psychologist provides continuous support to the project. Facilities at Kimbrough Army Hospital, Fort Meade, MD, are available if required.

10. (S/CL-3/NOFORN) CONFIDENTIALITY: Individuals performing as psychoenergetic trainees, sources, and monitors under the CENTER LANE Project will not have their roles identified outside of their parent organization without their specific prior consent, and they will be referred to in project reports only by an alpha-numeric designator. Products of CENTER LANE such as tapes, drawings, transcripts, rosters, or other materials which might reveal the identity of the source will be coded to assure the protection of their identity.

11. (S/CL-2/NOFORN) PHYSICAL ENVIRONMENT: Psychoenergetic sessions will be conducted in an ordinary room at ambient temperature and humidity during the normal waking hours of the participants. The only limitations on these parameters will be for security from electronic eavesdropping and elimination of ordinary distractions, such as radio, office machinery, and outside noises.

APPENDIX A

US ARMY
INTELLIGENCE AND SECURITY COMMAND
CENTER LANE TRAINING AND APPLICATIONS PROCEDURES

Historical Summary of "Human Use" Issue

WARNING NOTICE: CENTER LANE SPECIAL ACCESS PROGRAM
RESTRICT DISSEMINATION TO THOSE WITH VERIFIED ACCESS
TO CATEGORY TWO (2)

SENSITIVE INTELLIGENCE SOURCES AND METHODS INVOLVED

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APPENDIX A

Historical Summary of "Human Use" Issue

1. (S/CL-2/NOFORN) In February 1979, the Army General Counsel determined that GRILL FLAME activities involved testing on human subjects, [redacted] In March 1979, The Surgeon General's Human Subjects Research Review Board reviewed the GRILL FLAME protocol and concluded that it represented technology transfer and validation of the technology transfer, rather than research or clinical investigation, and as such, GRILL FLAME activities did not require approval for human use. However, the Board expressed concerns that future Army follow-on work might be classified as research, and as such, plans should be considered to establish credible human use review procedures to oversee GRILL FLAME activities. In April 1979, Army General Counsel determined that the Army could continue/proceed with GRILL FLAME activities as long as HEW guidelines and other appropriate precautionary measures were taken. In April 1980, the Under Secretary of the Army approved the continuation of GRILL FLAME activities. In October 1980, the DoD, DIA, and Army General Counsel jointly agreed that it would be prudent to obtain written approval from the Deputy Secretary of Defense to conduct GRILL FLAME activities. ACSI, DA concurrently initiated action to obtain Secretary of the Army approval to conduct GRILL FLAME activities. In September 1982, INSCOM GRILL FLAME activities ceased because of NFIP restrictions; INSCOM psychoenergetic activities were reinitiated in December 1982, under the INSCOM CENTER LANE Project (ICLP), an S&TA activity. Secretary or Under Secretary approval for GRILL FLAME/ICLP activities has been granted on 14 January 1981, 1 February 1982 and 1 September 1983. Approvals are generally valid for one year.

2. (U) Regulations governing "Experimentation on Human Subjects" are as follows:

a. (U) 45 Code of Federal Regulations, Part 46, "Protection of Human Subjects" (Incl 1).

b. (U) Procedure 13, DOD Directive 5240.1-R (Incl 2).

c. (U) AR 381-10, paragraph 2-18 (Incl 3).

d. (U) USAINSCOM Regulation 15-3, "Boards, Commissions and Committees: HIGH PERFORMANCE REVIEW PROCEDURES" (Incl 4).

OPRR Reports

NIH PHS HHS

PROTECTION OF HUMAN SUBJECTS

CODE OF FEDERAL REGULATIONS

45 CFR 46

Revised as of March 8, 1983

Approved For Release 2004/07/09 : CIA-RDP96-00788R001500090010-7

NATIONAL RESEARCH ACT

PUBLIC LAW 93-348

JULY 12, 1974

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 212. (a) Part F of title IV of the Public Health Service Act, as amended by section 103 of this Act, is amended by adding at the end the following new section:

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

"(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately."

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

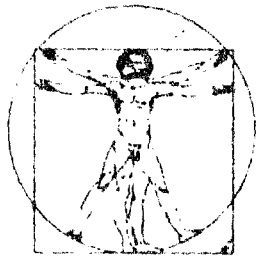
THE CODE OF FEDERAL REGULATIONS,
45 CFR 46, IMPLEMENTS THESE AMENDMENTS
TO THE PUBLIC HEALTH SERVICE ACT.

(also see audio cassette)

CODE OF FEDERAL REGULATIONS

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS



PART 46—PROTECTION OF HUMAN SUBJECTS
REVISED AS OF MARCH 8, 1983

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D—Additional Protections for Children Involved as Subjects in Research

Authority: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 289/-3(a)).

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Source: 46 FR 8386, January 26, 1981, 48 FR 9269, March 4, 1983.

§ 46.101 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.

(1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or funded by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of this section waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if

information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(c) The Secretary has final authority to determine whether a particular activity is covered by these regulations.

(d) The Secretary may require that specific research activities or classes of research activities conducted or funded by the Department, but not otherwise covered by these regulations, comply with some or all of these regulations.

(e) The Secretary may also waive applicability of these regulations to specific research activities or classes of research activities, otherwise covered by these regulations. Notices of these actions will be published in the *Federal Register* as they occur.

(f) No individual may receive Department funding for research covered by these regulations unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under an assurance satisfying the requirements of this part, or the individual makes other arrangements with the Department.

(g) Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

(h) Each subpart of these regulations contains a separate section describing to what the subpart applies. Research which is covered by more than one subpart shall comply with all applicable subparts.

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

§ 46.102 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Department" or "HHS" means the Department of Health and Human Services.

(c) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(d) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(e) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(h) "Certification" means the official notification by the institution to the Department in accordance with the requirements of this part that a research project or activity involving human subjects has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the approved assurance on file at HHS. (Certification is required when the research is funded by the Department and not otherwise exempt in accordance with § 46.101(b)).

§ 46.103 Assurances.

(a) Each institution engaged in research covered by these regulations shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in these regulations.

(b) The Department will conduct or fund research covered by these regulations only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Secretary that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. This assurance shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of these regulations applicable to Department-funded research and is not applicable to any research in an exempt category listed in § 46.101.

(2) Designation of one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Secretary.[1]

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv) for insuring prompt reporting to the IRB and to the Secretary[1] of unanticipated problems involving risks to subjects or others.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by these regulations, and shall be filed in such form and manner as the Secretary may prescribe.

(d) The Secretary will evaluate all assurances submitted in accordance with these regulations through such officers and employees of the Department and such experts or consultants engaged for this purpose as the Secretary determines to be appropriate. The Secretary's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Secretary may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Secretary may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Within 60 days after the date of submission to HHS of an application or proposal, an institution with an approved assurance covering the proposed research shall certify that the application or proposal has been reviewed and approved by the IRB. Other institutions shall certify that the application or proposal has been approved by the IRB within 30 days after receipt of a request for such a certification from the Department. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

§ 46.104 [Reserved]

§ 46.105 [Reserved]

§ 46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of these regulations each IRB shall:

(a) Follow written procedures as provided in § 46.103(b)(4).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Secretary[1] any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary has established, and published in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the *Federal Register*.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Secretary may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary.[1]

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

§ 46.114 Cooperative research.

Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible to the Department for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly from the Department, except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 46.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members as required by § 46.103(b)(3).

(6) Written procedures for the IRB as required by § 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to the Department with the knowledge that subjects may be involved within the

period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research described in § 46.101(b), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in these regulations, and certification submitted to the Department.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research (conducted or funded by the Department) is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in these regulations, a certification submitted to the Department, and final approval given to the proposed change by the Department.

§ 46.120 Evaluation and disposition of applications and proposals.

(a) The Secretary will evaluate all applications and proposals involving human subjects submitted to the Department through such officers and employees of the Department and such experts and consultants as the Secretary determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

(b) On the basis of this evaluation, the Secretary may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 Investigational new drug or device 30-day delay requirement.

When an institution is required to prepare or to submit a certification with an application or proposal under these regulations, and the application or proposal involves an investigational new drug (within the meaning of 21 U.S.C. 355(i) or 357(d)) or a significant risk device (as defined in 21 CFR 812.3(m)), the institution shall identify the drug or device in the certification. The institution shall also state whether the 30-day interval required for investigational new drugs by 21 CFR 312.1(a) and for significant risk devices by 21 CFR 812.30 has elapsed, or whether the Food and Drug Administration has waived that requirement. If the 30-day interval has expired, the institution shall state whether the Food and Drug Administration has requested that the sponsor continue to withhold or restrict the use of the drug or device in human subjects. If the 30-day interval has not expired, and a waiver has not been received, the institution shall send a statement to the Department upon expiration of the interval. The Department will not consider a certification acceptable until the institution has submitted a statement that the 30-day interval has elapsed, and the Food and Drug Administration has not requested it to limit the use of the drug or device, or that the Food and Drug Administration has waived the 30-day interval.

§ 46.122 Use of Federal funds.

Federal funds administered by the Department may not be expended for research involving human subjects unless the requirement of these regulations, including all subparts of these regulations, have been satisfied.

§ 46.123 Early termination of research funding; evaluation of subsequent applications and proposals.

(a) The Secretary may require that Department funding for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Secretary finds an institution has materially failed to comply with the terms of these regulations.

(b) In making decisions about funding applications or proposals covered by these regulations the Secretary may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not Department funds were involved).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Secretary may impose additional conditions prior to or at the time of funding when in the Secretary's judgment additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research Development, and Related Activities Involving Fetuses,[1] Pregnant Women, and Human In Vitro Fertilization[2]

SOURCE: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978, 43 FR 51559, November 3, 1978

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare

grants and contract supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following explusion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health, Education, and Welfare.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or

verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is

not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov 16, 1978

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health, Education, and Welfare involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "DHEW" means the Department of Health, Education, and Welfare.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to

all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHEW may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(A) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHEW shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions (1), (2), (5) and (6) as listed in Subpart A at § 46.101(b) are applicable to this subpart. Exemption (4), research involving the observation of public behavior, listed at § 46.101(b), is applicable to this subpart where the investigator(s) does not participate in the activities being observed. Exemption (3), research involving survey or interview procedures, listed at § 46.101(b) does not apply to research covered by this subpart.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.406.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §§ 46.404, 46.405, or 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of §§ 46.404, 46.405, or 46.406, as applicable, or (2) the following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment

may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §§ 46.404 or 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §§ 46.406 or 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

NOTICES

HUMAN SUBJECTS
Minimum Criteria Identifying the Viable Fetus

On March 13, 1975, regulations were published in the FEDERAL REGISTER (40 FR 11854) relating to the protection of human subjects in research, development, and related activities supported by Department of Health, Education, and Welfare grants and contracts. These regulations are codified at 45 CFR Part 46.

Elsewhere in this issue of the FEDERAL REGISTER, the Secretary is amending 45 CFR Part 46 by, among other things, adding a new Subpart B to provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization.

Section 46.203(d) of Subpart B provides inter alia as follows:

The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart.

This notice is published in accordance with § 46.203(d). For purposes of Subpart B, the guidelines indicating that a fetus other than a dead fetus within the meaning of § 46.203(f) is viable include the following:

an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more.

FEDERAL REGISTER, VOL 40, AUGUST 8, 1975

U.S. GOVERNMENT PRINTING OFFICE : 1983 O - 406-756

PROCEDURE 13. EXPERIMENTATION ON HUMAN SUBJECTS FOR INTELLIGENCE PURPOSES

A. APPLICABILITY

This procedure applies to experimentation on human subjects if such experimentation is conducted by or on behalf of a DoD intelligence component. This procedure does not apply to experimentation on animal subjects.

B. EXPLANATION OF UNDEFINED TERMS

1. Experimentation in this context means any research or testing activity involving human subjects that may expose such subjects to the possibility of permanent or temporary injury (including physical or psychological damage and damage to the reputation of such persons) beyond the risks of injury to which such subjects are ordinarily exposed in their daily lives.

2. Experimentation is conducted on behalf of a DoD intelligence component if it is conducted under contract to that component or to another DoD component for the benefit of the intelligence component or at the request of such a component regardless of the existence of a contractual relationship.

3. Human subjects in this context includes any person whether or not such person is a United States person.

C. PROCEDURES

1. Experimentation on human subjects conducted by or on behalf of a DoD intelligence component may be undertaken only with the informed consent of the subject, and in accordance with guidelines issued by the Department of Health and Human Services, setting out conditions that safeguard the welfare of such subjects.

2. DoD intelligence components may not engage in or contract for experimentation on human subjects without approval of the Secretary or Deputy Secretary of Defense, or the Secretary or Under Secretary of a Military Department, as appropriate. [Requests for such approval submitted by Army intelligence components will be addressed through command channels to HQDA (DAMI-CIC), WASH DC 20310.]

DEPARTMENT OF DEFENSE

PROCEDURES GOVERNING THE ACTIVITIES OF DOD INTELLIGENCE COMPONENTS THAT AFFECT UNITED STATES PERSONS

DECEMBER 1982

UNDER SECRETARY OF DEFENSE FOR POLICY

Encl 2

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This procedure applies to experimentation on human subjects if such experimentation is conducted by or on behalf of a DoD intelligence component. This procedure does not apply to experimentation on animal subjects.

B. EXPLANATION OF UNDEFINED TERMS

1. Experimentation in this context means any research or testing activity involving human subjects that may expose such subjects to the possibility of permanent or temporary injury (including physical or psychological damage and damage to the reputation of such persons) beyond the risks of injury to which such subjects are ordinarily exposed in their daily lives.

2. Experimentation is conducted on behalf of a DoD intelligence component if it is conducted under contract to that component or to another DoD component for the benefit of the intelligence component or at the request of such a component regardless of the existence of a contractual relationship.

3. Human subjects in this context includes any person whether or not such person is a United States person.

C. PROCEDURES

1. Experimentation on human subjects conducted by or on behalf of a DoD intelligence component may be undertaken only with the informed consent of the subject, in accordance with guidelines issued by the Department of Health and Human Services, setting out conditions that safeguard the welfare of such subjects.

2. DoD intelligence components may not engage in or contract for experimentation on human subjects without approval of the Secretary or Deputy Secretary of Defense, or the Secretary or Under Secretary of a Military Department, as appropriate.

personnel may be provided by Army intelligence components to state and local law enforcement authorities only when lives are endangered and only pursuant to a request by the head of such authority. Such requests must be approved by the Secretary or Under Secretary of the Army. Under these circumstances expert personnel may be provided to such agency provided participation in law enforcement activities is limited as follows:

(*a*) Only personnel with technical skills not readily available to such law enforcement authorities, which can be utilized to prevent death or serious injury, may be provided;

(*b*) Provision of such personnel will be limited to that necessary to prevent the death or serious injury that is threatened, but in no case shall such assistance be provided for more than 72 hours;

(*c*) Such personnel are not used to apprehend persons who are suspected of committing, or who are about to commit, a crime, or

(*d*) Use of such personnel does not violate the Posse Comitatus Act.

(3) *Emergency assistance.* In emergency situations, where life is endangered, the request required in (1) and (2) above may be oral, provided that it is reduced to writing and submitted to HQDA(DAMI-CIC) within 72 hours. Where life is endangered, doubt as to the legality and propriety of the requested assistance under this procedure should be resolved in favor of providing the assistance.

2-17. **Procedure 17. Assignment of intelligence personnel to other agencies.** *a. Applicability and scope.* This procedure applies to the assignment of DA intelligence personnel to other agencies within the federal government. This procedure does not apply to--

(1) Assignment to state or local governments, corporations or other private organizations.

(2) Assignment to another agency within the intelligence community when part of the purpose of the assignment is to gain experience and knowledge about the activities of the other agency. (Reporting or report in this context means transmittal of information about the operation or personnel of an agency that is not available publicly.)

b. Policy. Employees of Army intelligence components who are assigned to work for and under the direction of another agency of the federal government will conduct themselves for the duration of their assignment as if they were employees of that agency. Any responsibilities to provide information to or services for DA will be stated expressly and made a part of the terms of the assignment.

c. Procedures.

(1) Assignment of employees of Army intelligence components to other agencies within the federal government is governed by DOD Directive 1000.17. The memorandum of agreement concerning such assignment and required by subsection D(6)(*c*)(1) of the Directive shall include--

(*a*) An identification of the Army intelligence component from which the employee has been assigned by DA.

(*b*) A statement delineating the employee's responsibilities, if any, for reporting to the DA about matters that come to the employee's attention while on assignment outside the Department.

(2) Other than is permitted by the terms of the memorandum of agreement pursuant to DoD Directive 1000.17, an employee of an Army intelligence component on assignment to another agency of the federal government may not report to any Army component the operations or personnel of the agency to which the employee is assigned.

(3) After completion of an assignment to another agency of the federal government and return to DA, an employee remains under the same restrictions, as to reporting, that applied when the employee was on such assignment.

2-18. **Procedure 18. Experimentation on human subjects.** *a. Applicability and scope.*

(1) This procedure applies to experimentation on human subjects if such experimentation is conducted by or on behalf of any Army intelligence component. This procedure does not apply to experimentation on animal subjects.

Incl 3

(2) Experimentation in this context means a research, development, or related activity that may expose an individual to the possibility of injury (including physical, psychological, or social injury) that increases the ordinary risks of daily life for the subject (including the recognized risks inherent in a chosen occupation or field of service), or that temporarily adversely affects a person's mental or physical condition.

(3) Experimentation is conducted "on behalf of" an Army intelligence component if it is conducted under contract to that component or to another Army component for the benefit of the intelligence component, or at the request of such a component regardless of the existence of a contractual relationship.

(4) Human subjects in this context includes any person regardless of whether the person qualifies as a US person.

b. Policy. Army intelligence components may conduct experimentation on human subjects only when an important foreign intelligence or CI purpose is to be served, only after the informed consent of the subject has been obtained in writing, and only in accordance with guidelines issued by the Department of Health and Human Services setting out conditions that safeguard the welfare of the subjects, and other applicable regulations.

c. Procedure. Army intelligence components may not engage in or contract for experimentation on human subjects without prior approval of the Secretary or Under Secretary of the Army.

2-19. Procedure 19. Special activities. *a. Applicability and scope.*

(1) This procedure applies to the conduct and support of special activities by Army intelligence components. This procedure also applies to other Army components that provide support for special activities conducted by DoD intelligence components and other agencies within the Intelligence Community. These procedures *do not* apply to—

(*a*) Diplomatic or military attache activities conducted by DOD.

(*b*) The collection and production of intelligence;

(*c*) Any functions in support of the collection and production intelligence; or

(*d*) The conduct of special activities by the military services in armed conflict or to military deception operations targeted, for military purposes, against a hostile foreign power.

(2) Conspiracy in this context has the same meaning as in the criminal law context and requires an overt act. Neither the term "assassination" nor the term "conspire" include military or civilian measures against ongoing international terrorist activities (which is a defined term (see glossary) and should be construed strictly), aircraft hijackings, or in response to danger of substantial physical harm to any person. These terms do not apply to actions of the military services in the execution of lawfully ordered military operations.

(3) Diplomatic and military attache activities means the representational, information gathering, and reporting activities performed by diplomatic and military attache personnel abroad.

(4) Production of intelligence means the process of developing "intelligence products" which is a defined term. (see glossary).

(5) Special activities mean activities conducted abroad in support of national foreign policy objectives that are designed to further official US programs and policies abroad; that are planned and executed so that the role of the United States Government is not apparent, or acknowledged publicly and functions in support of such activities, but not including diplomatic and military attache activities or the collection and production of intelligence or related support functions.

(6) Support, when used in this context, means the provision of assistance in the form of transportation, training, supplies, equipment or expert personnel.

b. Policy. No Army intelligence component will participate in the conduct or support of special activities. No other Army component will provide support for special activities except upon the specific direction of the Secretary or Under Secretary of the Army and the Secretar

DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
Arlington Hall Station
Arlington, Virginia 22212

USAINSCOM Regulation 15-3

24 February 1984

Boards, Commissions and Committees
HIGH PERFORMANCE REVIEW PROCEDURES

During 1982 and 1983, in keeping with the US Army Intelligence and Security Command (INSCOM) goal of "extraordinary performance," and seeking to move the command to a level which exceeds commonly defined parameters of performance, the INSCOM conducted a study of high performing organizations and programs in the public and private sectors. Several technologies, management techniques, training experiences and programs were identified for further evaluation with respect to their potential to contribute to the development of extraordinary individual and unit performance within the Command. This regulation contains INSCOM policies and guidance for that evaluation, establishes procedures for the use of INSCOM personnel as volunteers in evaluating and implementing high performing human systems and provides guidance for commanders and supervisors in further implementing and evaluating those high performing human systems. Supplementation of this regulation is permitted only after prior approval has been obtained from this Headquarters, ATTN: IASJA.

Chapter 1

GENERAL INFORMATION

1-1. Purpose. This regulation contains INSCOM policies and guidance for the evaluation and implementation of high performing human systems within the command. It --

a. Promulgates procedures and guidance for the use of INSCOM personnel as volunteers in the evaluation of high performing human systems;

b. Establishes and implements a review process which is consistent with AR 70-25;

c. Insures the continued evaluation of INSCOM activities to assure that the provisions of AR 70-25 are being followed;

d. Establishes procedures to obtain a health hazard assessment prior to approving an INSCOM protocol issued as required herein; and

e. Promulgates INSCOM policies and procedures to assure that INSCOM components do not engage in or contract for experimentation on human subjects in violation of Procedure 13, AR 381-10.

1-2. Applicability. This regulation applies to all elements of the INSCOM.

1-3. References.

a. AR 70-25, Use of Volunteers as Subjects of Research.

b. AR 381-10, US Army Intelligence Activities.

c. AR 70-31, Standards for Technical Reporting.

1-4. Scope.

a. Nothing in this regulation is intended to supersede requirements for health hazard or other safety reviews required by any other regulations or directives.

b. The procedures, policies and guidance contained in this regulation pertain to the following:

(1) Behavioral studies, research and/or testing involving human subjects, regardless of whether conducted by INSCOM, a contractor, or other agency utilizing INSCOM funds.

(2) Inclusion of human subjects, whether as the direct or indirect object of research, regardless of the level or risk involved, in the development, testing or study of matters associated with the missions and functions of

the INSCOM, or the application of non-traditional ideas and technologies in achieving high performance of human resources.

(3) The investigation of programs and technologies to enhance organizational and individual excellence where such investigation involves the inclusion of human subjects as their object.

1-5. Exemptions.

a. Research, testing and studies in which human subjects are involved in one or more of the following categories are exempt from this regulation.

(1) Bonafide activities under the sponsorship of another Department of the Army component and involving surveys or interviews where all of the following conditions exist:

(a) Responses are recorded in such a way that subjects cannot be identified directly or indirectly.

(b) The subject's responses, if they become known, would not place the subject at risk of criminal or civil liability or damage the subject's financial or social standing or employability.

(c) The activity does not deal with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(2) Research which involves the use of educational tests, provided the data is recorded in such a way that the subjects cannot be identified directly or indirectly.

(3) Research in non-INSCOM educational settings which involve normal educational practices, such as --

(a) Regular and special educational strategies.

(b) The effectiveness or the comparison among techniques of instruction, curricula, or classroom methods.

(4) Follow-up debriefings, interviews, tests, or evaluations to determine how well participants have learned the information or skills transmitted by training or instructional activities previously attended by the subject thereof.

b. Exemptions of other activities from this regulation, even where such activities may be exempted from other similar regulations or directives, shall not be considered valid for INSCOM purposes unless and until confirmed by the INSCOM Human Technology Review Board as prescribed elsewhere in this regulation.

Chapter 2

RESPONSIBILITIES

2-1. Approving officials. The Commanding General, the Deputy Commander, Intelligence, and the Deputy Commander, Support, are the designated INSCOM approving officials. Only these officials may approve the use of human subjects in research.

2-2. Commanders and Staff Element Heads. Commanders at all levels within the INSCOM, heads of Headquarters staff elements, office chiefs and program directors (hereinafter referred to only as commanders and staff element heads) are responsible within their respective functional areas for --

a. Insuring that the provisions of this regulation are institutionalized into their organizational procedures and practices.

b. Insuring that no persons engage in or contract for experimentation involving human subjects without the express approval of an INSCOM approving official.

2-3. INSCOM Human Technology Review Board (HTRB). The INSCOM HTRB is responsible for --

a. Observing written procedures for the following:

(1) Initial and continuing review of research, including the reports of findings and actions to the investigator and the approving official.

(2) Determination of those projects which must be --

(a) Reviewed more often than annually.

(b) Verified from sources other than the investigators that no material changes have occurred since the previous HTRB review.

(3) Prompt reporting to the HTRB of proposed changes in the research, and to the HTRB and approving official of unexpected problems involving risks to the subjects or others.

b. Insuring that changes in approved projects (during the period for which approval has already been given) are not initiated without HTRB review, except to eliminate immediate hazards to a subject.

c. Reviewing proposed protocols at meetings attended by a majority of members except when an expedited review is used. For the protocol to be approved, it will receive the approval of a majority of those members present.

d. Reporting to the CG any serious or continuing noncompliance with HTRB requirements and determinations found by investigators.

e. Conducting a continuous review of research studies at intervals proper to the degree of risk, but not less than once per year.

f. Insuring the observation by a third party of the consent process and each investigation, as appropriate.

g. Recommending safeguards or special conditions to a protocol. When such recommendations are made, the approving official may take the following action:

(1) Not reduce the safeguards or conditions, and approve the protocol.

(2) Require additional safeguards.

(3) Disapprove the protocol.

(4) Refer the protocol to a higher echelon approving authority for action and review.

2-4. Chairperson of the HTRB. The DCSPPM is designated Chairperson and a regular member of the HTRB and is responsible for chairing HTRB meetings, keeping the CG informed of HTRB activities, and recommending approval/disapproval of HTRB regular members to the CG.

2-5. Executive Secretary of the HTRB. The DCSPPM will designate a member of his staff to be the Executive Secretary of the HTRB. The Executive Secretary of the HTRB is responsible for --

a. Insuring that the responsibilities of the HTRB prescribed in paragraph 2-3 are carried out.

b. Preparing and distributing the agenda for each meeting to all HTRB members.

c. Insuring that all HTRB members are afforded the opportunity to comment on HTRB actions conducted under expedited review procedures.

2-6. Regular HTRB membership. The INSCOM DCSOPS, DCSPER, DCSSYS, SJA, Command Chaplain and DARCOM LNO, are each responsible for nomination of an individual to serve as a regular member of the HTRB. Nominees may be from their respective staffs, subordinate command functional counterpart staffs, or may be the nominating element head. Nominations will be submitted to the HTRB Chairperson (DCSPPM) for approval/disapproval by the CG. Nominations may be by letter, DF or message, and will contain the information required by paragraph a, below.

a. Nominees will be identified by name, earned degrees, current position and duties, and experience, such as board certifications and licenses. The information in the nomination will be complete enough to describe each member's chief expected contributions to HTRB reviews.

b. Nominees will normally be military officers in the grade of O-5, or above, or civilian employees, GS-13 or above. Nominees will have diverse backgrounds to insure thorough review of research studies involving human volunteers as research subjects. Nominees should be of varied racial and cultural backgrounds. Nominees should have displayed sensitivity to such issues as community attitudes, and respect for advice and counsel and for the rights and welfare of human subjects.

c. Confirmed nominees will serve as HTRB members for an indefinite term, and will be expected to have final authority to speak on behalf of their activity.

2-7. Ex officio HTRB membership. The incumbents of the following positions will serve as ex officio, non-voting members of the HTRB:

a. Chief, CENTEX.

b. Command Psychologist.

c. Chief, Human Technology Office.

d. Chief, Public Affairs Office.

2-8. Ad hoc HTRB membership. The following will serve as ad hoc members of the INSCOM HTRB:

a. The Staff Advisor for Scientific and Cryptologic Affairs.

b. A physician, as approved by an INSCOM approving official (para 2-1). Physician nominees for ad hoc membership will be provided as requested by the Chairperson.

2-9. Principal investigator. The principal investigator for each project covered by this regulation is responsible for --

a. Maintaining adequate records on the following:

(1) Receipt, storage, use and disposition of all investigational materials and devices.

(2) Case histories that record all observations and other data important to the study.

(3) Volunteer agreement documents.

b. Preparing progress reports, including annual reports, as determined by the approving authority and the INSCOM HTRB.

c. Promptly notifying the approving authority, through the INSCOM HTRB, of any adverse effects caused by the research.

d. Insuring that the research has been approved by the proper authority and the INSCOM HTRB before starting, changing or extending a study.

e. Insuring that all subjects, including those used as controls or their representatives, are fully informed of the nature of the research to include potential risks to the subject.

f. Insuring that investigational materials and devices are administered only to subjects under his or her personal supervision and that of a previously approved associate investigator.

g. Insuring that volunteer recruiting teams are briefed as to the nature of the research and the ethical principles in this and related regulations.

2-10. Members of volunteer recruiting teams. Members of volunteer recruiting teams are responsible for --

a. Establishing volunteer requirements prior to recruitment.

b. Undertaking recruiting in a morally, ethically and legally acceptable manner.

2-11. Medical monitor. The medical monitor of each project is responsible for and is hereby delegated the authority to terminate the effort if --

a. Subjects are at risk of life or limb.

b. It appears the risk is significantly greater than anticipated at the time of review and approval of the project.

Chapter 3

POLICIES

3-1. General. Experimentation involving human technology or human subjects conducted by or on behalf of any INSCOM component may be undertaken only with the informed consent of the subject, and in accordance with guidelines issued by the Department of Health and Human Services (DHHS), setting out conditions that safeguard the welfare of such subjects. The provisions of this regulation constitute INSCOM implementation of those guidelines.

3-2. Approval. INSCOM components may not engage in or contract any research or testing involving human subjects without advance approval through the INSCOM HTRB by an INSCOM approving official, or higher level official, where appropriate. This approval is required regardless of the degree of risk involved.

3-3. Risk determinations. The INSCOM HTRB will render all risk determinations regarding INSCOM research or testing involving human subjects.

3-4. Risk versus benefit. The degree of potential risk involved in any project will never exceed the expected benefits of that effort.

3-5. Moral, ethical and legal concepts. The moral, ethical and legal concepts on the use of human subjects will be followed as outlined in this regulation. Voluntary consent of each human subject is essential. Military personnel are not subject to the Uniform Code of Military Justice (UCMJ) for choosing not to take part as human subjects.

3-6. Fully informed subjects. Only persons who are fully informed and volunteer to take part may be used as human subjects in INSCOM research and testing activities.

3-7. Use of non-US citizens. Research may be conducted outside the US that involves non-US citizens; however, all requirements of this regulation applicable to human subjects shall be equally applicable to non-US citizen human subjects.

3-8. Use of prisoners of war and detainees. The use of prisoners of war and detainees as human research subjects is prohibited.

3-9. Medical care. Volunteers will be authorized all necessary medical care for injury or disease that is the proximate result of taking part in approved INSCOM research or testing activities.

3-10. Stated objectives. Each project will be designed to achieve its stated objectives. The proposed number of subjects will be the minimum needed to insure that statistically significant results are obtained.

3-11. Physical and mental suffering. Each project will be conducted in such a manner as to avoid unnecessary physical and mental suffering. Preparations

will be made and adequate facilities provided to protect the subject and investigators against all foreseeable injuries, disabilities, or death. A project will not be conducted if any reason exists to believe that death or injury will result. The degree of potential risk will never exceed the expected benefits of the project.

3-12. Qualifications of investigators. Only persons judged qualified by the appropriate approving authority will conduct human subject studies. The physician responsible for the health and welfare of the subject may or may not be the principal investigator. The physician is authorized to stop the project at any time he or she believes that injury, disability or death may result.

3-13. Minors. Minors may not be involved as human research subjects without advance approval in each case by the INSCOM HTRB.

3-14. Recruiting of volunteers. Volunteer recruiting will be accomplished by personnel responsible for the conduct of the particular project, or as otherwise specifically approved by the INSCOM HTRB.

3-15. Protocol guidance.

a. Each approved protocol will be reviewed at least annually and on a continuing basis as determined by the INSCOM HTRB. Annually means once each 12-month period.

b. The decision as to whether a research protocol involves more than minimal risk shall be made by the INSCOM HTRB.

c. The research protocol will be prepared in accordance with the instructions contained at appendix B.

Chapter 4

PROCEDURAL GUIDANCE

4-1. Technical reports. Technical reports will be prepared as prescribed in AR 70-31 and follow the format of MIL-STD-847A. When applicable, these reports will contain the following statement:

> For the protection of human subjects, the investigators have adhered to the policies of AR 70-25 concerning the use of volunteers as research subjects.

4-2. Advising the Medical Research and Development Command. Two copies of technical reports of study will be forwarded to the Commander, US Army Medical Research and Development Command, ATTN: SGRD-HR, Fort Detrick, Frederick, Maryland 21701. When HQDA approval, or higher, is required, information copies of material forwarded for approval will also be furnished to the office above. These will include as a minimum, two copies of the protocol, a copy of the volunteer agreement and all minutes of INSCOM HTRB meetings reviewing the proposed project.

4-3. Informed consent. Subjects will be given adequate time to review and understand all information before agreeing to take part in a project. The volunteer agreement documents will be written in language that is easily understood by the subject. The documents listed below will be discussed with each subject before his or her acceptance.

a. The Volunteer Agreement (appendix C).

b. The Explanation Portion of the Volunteer Agreement (appendix D).

4-4. Minimum standards. The laws, customs and practices of the country in which the research is conducted will take precedence over procedures required by this regulation, where applicable. The project must meet the same standards of ethics and safety, however, that apply within the US involving US citizens. When standards vary, the more stringent will apply. A minimum age of 18 is required for US citizens taking part in research conducted outside the US, regardless of the laws of the country in which the effort is being undertaken.

4-5. More than minimal risk. When it has been determined that the risk in a human subjects study is more than minimal, then advance approval is required through HQDA (DAMI-CI) by the Secretary or Under Secretary of the Army. In addition, a medical monitor shall be recommended by the INSCOM HTRB and approved by the CG.

4-6. Contractors or vendors. Contractors or vendors holding approved DHHS assurance of compliance shall be considered in compliance with this regulation. In the absence of such an assurance, a special assurance will be negotiated

with the contractor or vendor. In all cases, however, the INSCOM HTRB must approve the INSCOM participation in or utilization of such contractors or vendors.

4-7. Requests for exceptions. Requests for exceptions to this regulation will be submitted to the INSCOM HTRB Chairperson (DCSPPM) with full justification.

4-8. Expedited review categories. Categories which may be processed in the expedited review procedures are as follows:

a. Recording of data from subjects who are 18 years of age or older, using non-invasive procedures routinely employed in clinical practice. This category does not include exposure to electromagnetic radiation outside the visible range (e.g., X-rays, microwaves). It does include --

(1) The use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy.

(2) Such procedures as --

(a) Weighing.

(b) Electrocardiography.

(c) Electroencephalography.

(d) Thermography.

(e) Detection of naturally occurring radioactivity.

(f) Diagnostic echography.

(g) Electroretinography.

b. Voice recordings made for research purposes such as investigations of speech defects, improvement in language utilization, etc.

c. Moderate exercise of healthy volunteers.

d. Study of existing data, documents, records, pathological specimens, or diagnostic specimens.

e. Minor changes in previously approved research during the period for which approval has been authorized.

4-9. Expedited review procedures. Under an expedited review procedure, the HTRB Chairperson, or one or more HTRB reviewers designated by the chairperson, may carry out the review. These reviewers may exercise all of the authorities

of the HTRB except that of disapproval, which may only be exercised as prescribed elsewhere in this regulation.

a. When the expedited review procedure is used, the reviewers will furnish complete copies of all their actions and related materials (e.g., research plan, protocol, etc.) to all other members of the HTRB. The HTRB Chairperson will submit a written report of expedited review actions to the CG within ten working days of approval action.

b. An expedited review procedure may be restricted or suspended to protect the rights or welfare of subjects at any time based upon either direction of an approving official or request by any member of the HTRB.

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Chapter 5

INSCOM HUMAN TECHNOLOGY REVIEW BOARD ACTIVITIES

5-1. Composition of the HTRB. Membership in the INSCOM HTRB will consist of the chairperson; at least six other regular members, appointed by the CG from among the nominations submitted in accordance with paragraph 2-6 and 2-8, above, or from other sources; an executive secretary; and such other ex officio and ad hoc members as prescribed in chapter 2, above. One regular member will be not affiliated with the INSCOM and not part of the immediate family of a person affiliated with the INSCOM.

5-2. General criteria for membership. At least one member of the HTRB will be from a profession/position/activity primarily concerned with the welfare of human persons. At least one member will be non-scientific, such as a lawyer, ethicist or member of the clergy. THE INSCOM HTRB may invite persons with special competence to assist in the review of complex issues that require expertise beyond that available on the HTRB. These persons normally will not vote, unless he or she is serving as the non-INSCOM member of the HTRB.

5-3. General committee activities. Each regular and ad hoc committee member shall have one equal vote, and the entire committee will be vested with the responsibility to determine if a proposed activity is acceptable. Acceptability will be in terms of Army Medical Department (AMEDD) commitments and regulations, applicable law, standards of conduct and practice, and with full consideration for the particularly sensitive nature of the INSCOM's role as an intelligence component.

a. At least five voting members will be required to constitute a quorum at each committee meeting.

b. All actions of the committee will be by majority vote of members present.

5-4. Avoiding possible conflicts of interest.

a. Except to provide information requested by the HTRB, no INSCOM HTRB member may take part in a review of any project which is sponsored by that member's organization or office of employment or assignment, or in which there may otherwise be a conflict or appearance of a conflict of interest.

b. The intended approving official may not be a member of the HTRB. The approving official may not approve research for which he or she is also a principal or associate investigator. A higher echelon of command must review and approve such projects.

5-5. Criteria for INSCOM HTRB approval.

a. In evaluating the risks and benefits for projects under consideration, the INSCOM HTRB should consider only those that may result from that

particular project, unless a clear linkage has been established to other projects.

b. To approve an effort covered by this regulation, the INSCOM HTRB must determine that all of the requirements below are met.

(1) Risks to subjects are minimized by using procedures that are --

(a) Consistent with sound investigation design and do not unnecessarily expose subjects to risk.

(b) Already being used on subjects for diagnosis or treatment, when appropriate.

(2) Risks to subjects are reasonable in relation to --

(a) Anticipated benefits, if any, to the subjects.

(b) The importance of the knowledge that may be expected to result.

(3) In making an assessment for the selection of subjects, the sponsor has adequately considered --

(a) The purpose of the investigation.

(b) The setting in which the research investigation will be conducted.

(4) Informed consent will be secured from each subject.

(5) Informed consent will be properly documented.

(6) The protocol takes adequate provisions for monitoring the data collected to insure the safety of the subjects.

(7) Adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data when appropriate.

5-6. Special considerations of sensitivity. Some or all of the subjects may be vulnerable to special considerations of sensitivity because of past assignments, affiliations, etc. In such cases, additional safeguards will be included to protect the rights and welfare of these subjects. In no instance will the INSCOM be a party to any research which involves the use of persons with acute or severe physical or mental illness, or those who are economically or educationally disadvantaged.

5-7. Suspension or termination of a project.

a. The INSCOM will suspend or terminate a project that --

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(1) Is not being conducted according to the HTRB's requirements.

(2) Has been associated with unexpected harm to the subjects.

b. Suspensions or terminations of a project will include a statement of the reasons for the HTRB's action, and will be reported within 24 hours to the principal investigator and the approving official.

5-8. Records.

a. The HTRB executive secretary will prepare and maintain adequate documents on HTRB activities, including —

(1) Copies of all proposals reviewed, scientific evaluations that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries and adverse reactions.

(2) Minutes of HTRB meetings showing attendance; actions taken by the INSCOM HTRB; the vote of these actions, including the number of members voting for, against, and abstaining a decision; the basis for requiring changes or disapproving a project; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the HTRB and project investigators.

(5) A current list of HTRB members. Members will be identified by name, earned degrees, representative capacity and experience, such as board certifications and licenses. The information will be complete enough to describe each member's chief expected contributions to HTRB reviews. Any employment or other relationship between members and the INSCOM will be noted.

(6) Written procedures, including agendas, expedited review procedures, etc., for the HTRB.

(7) Statements of significant new findings.

b. The records required by this regulation will be retained permanently under AR 340-18-13. Such records will be reasonably accessible for inspection and copying by authorized DA personnel and representatives of the Federal Food and Drug Administration.

APPENDIX A

TERMS AND ABBREVIATIONS

Section I - Terms

A-1. Approving official. The INSCOM Commanding General, Deputy Commander, Intelligence, Deputy Commander, Support, or higher level official, who has been delegated authority to approve the use of human subjects in research.

A-2. Associate investigator. A person who may be deeply involved in the execution of research but does not have overall primary responsibility.

A-3. Consent. The legally effective agreement to take part as a human subject. The agreement may pertain to one's own participation or be in behalf of another person. Three terms associated with this meaning that distinguish between the legal validity of such agreements are subject consent, permission, and assent. These terms are defined below.

a. Subject consent. Agreement by an adult person who has autonomous legal capacity to consent to taking part as a human subject. This form of consent pertains only to adults who have not lost their legal capacity to consent.

b. Permission. Agreement by a "legally authorized representative" for taking part as a human subject of another person who does not possess autonomous legal capacity to consent in his or her own behalf. A legally authorized representative is a person or judicial body authorized under applicable law to grant permission (also known as third-party consent).

c. Assent. The affirmative agreement to take part as a human subject by a person not possessing autonomous legal capacity to consent in his or her own behalf, but who is capable of understanding what is proposed and able to express an opinion as to willingness to participate. Assent is concurrence in what is proposed, but is not a substitute for subject consent because, unlike consent, assent has no legal effect.

A-4. Experimentation. Any research or testing activity involving human subjects that may expose such subjects to the possibility of permanent or temporary injury (including physical or psychological damage and damage to the reputation of such persons) beyond the risks of injury to which such subjects are ordinarily exposed in their daily lives.

A-5. Expedited review procedures. Those procedures used in research involving no more than minimal risk and those used for minor changes in approved investigations. These procedures minimize time required for review.

A-6. Health care practitioner. An individual trained to interact with patients to provide diagnostic or treatment procedures within established professional standards.

A-7. Human subject. Any person, whether or not such person is a US citizen, about whom an investigator conducting research, testing or studies obtains data through interaction with that person. Both physical procedures and manipulations of the subject or the subject's environment are included. Human subjects may be thought of as direct objects when the research is to determine the effects of a new system on man (for example, the psychological effects of a particular interrogation technique on an individual) or as indirect objects when a test is conducted to determine how man affects the ultimate performance of a system (doctrine, concepts, training programs).

A-8. Human Technology Review Board (HTRB). A body set up to provide initial and continuing review of research involving the use of human subjects. HTRB fulfills all the functions of a human use committee as described in AR 70-25. It is fundamentally similar to an Institutional Review Board (IRB) discussed in guidelines issued by the DHHS for human research, but has somewhat different authority as compared to an IRB. Within DOD, authority to approve the use of human subjects in research is vested in commanders. In the INSCOM it is vested in the CG, and has been delegated to the DCG-I and DCG-S for matters under their respective functional control. Approving officials act on recommendations of validly constituted HTRBs. Outside DOD, IRBs tend to be vested with this authority.

A-9. Legally authorized representative. A person or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject taking part in the procedures involved in the research.

A-10. Medical monitor. This person is a military or Department of the Army civilian physician who is responsible for observing human subjects during the conduct of research.

A-11. Minimal risk. When used in the context of this regulation, this means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

A-12. Principal investigator. A person, regardless of title, who is primarily responsible for the actual execution of the research.

A-13. Protocol. The written, detailed plan by which research is to be conducted. The plan contains, as a minimum, discussion of --

a. The objectives of the project.

b. The information to be collected.

c. The means by which it will be collected and evaluated.

d. An assessment of potential risks and benefits to subjects.

e. Safety measures.

f. Other means to be used to reduce the risks to subjects.

A-14. Research. A systematic investigation designed to develop or contribute to general knowledge concerning military or intelligence problems. The term does not include individual or group training of personnel such as combat readiness, effectiveness, proficiency or fitness exercises. This definition is unique to this regulation and is not intended to identify an effort for funding under appropriations intended for Research, Development, Test and Evaluation (RDTE). "Research" in the sense applied in this regulation will be funded according to the project, effort, etc., to which it applies.

A-15. Research and development. Any scientific inquiry, investigation, or validation performed or directed to test hypotheses or develop concepts concerning physical or biological principals or laws. Research is a major exploration of the unknown and contains unpredictable elements. Development usually is confined to the qualification or elaboration of known principals.

A-16. Systematic investigation. A formal inquiry generally described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The term includes clinical investigations, but does not include post-training or post-therapeutic inquiries intended only to evaluate individual progress or responsiveness to training or therapy.

A-17. Test and evaluation. An effort or assessment to validate proposed or existing standards or concepts of performance, either of humans or of material.

A-18. Test participants. Humans directly involved in test and evaluations, but who are not themselves the direct object of such activities. Generally, test participants are not regarded as receiving any direct benefits as a result of their participation in the test (for example, a new doctrine or training concept).

Section II - Abbreviations

ACSI	Department of the Army Assistant Chief of Staff, Intelligence
AMED	Army Medical Department
ARI	US Army Research Institute for the Behavioral and Social Sciences
CENTEX	The INSCOM Center for Excellence
CFR	Code of Federal Regulations
DA	Department of the Army
DARCOM	US Army Materiel Development and Research Command
DCSPER	The INSCOM Deputy Chief of Staff for Personnel
DCSPPM	The INSCOM Deputy Chief of Staff for Plans, Programs and Modernization
DCSOPS	The INSCOM Deputy Chief of Staff for Operations
DHHS	Department of Health and Human Services
HPTF	The INSCOM High Performance Task Force (no longer constituted)
HTRB	The INSCOM Human Technology Review Board
INSCOM	US Army Intelligence and Security Command
MACOM	Major Army command
SJA	The INSCOM Staff Judge Advocate
TSG	The Surgeon General of the Army
US	United States

APPENDIX B

FORMAT FOR PREPARATION OF A RESEARCH PROTOCOL

Section I

GENERAL INFORMATION

1. Project title. (Enter complete project title - if this is an amendment to an existing project, identify by indicating "Amendment No.____to" immediately preceding the title).

2. Investigators.

a. Principal investigator. (Enter full name, rank, title, organization and telephone number).

b. Associate investigators. (Identify all associate investigators and area of the project for which each is responsible. Include full name, rank, title, organization and telephone number for each).

3. Location of the project. (Identify all locations at which the project will be carried out and specify which portions will be done at each location and who is the point of contact at each location. Include telephone number for POC).

4. Period covered by the project. (Give month and year of expected start and completion dates).

Section II

INTRODUCTION

5. Synopsis.

a. (Enter a short, one-page or one-paragraph, summary of the proposed project, similar to the abstract of a scientific paper).

b. (Enter a list and brief description of safety measures for human subjects involved in the project).

6. Medical application. (Explain briefly the medical importance, including psychological considerations, and possible usefulness of the project).

7. Objectives. (State briefly but specifically the objectives of the project. Include items below, where applicable).

a. Study design. (Double-blind, crossover, etc.).

b. Technologies to be employed. (List the generic technologies to be employed in the project).

c. Type of population involved. (List the subject population to be observed).

8. Status. (State what has been accomplished or published in the proposed area of study and describe how this project will relate to, differ from and/or advance that which has already been accomplished).

9. Bibliography. (List all references used in preparing the protocol).

10. Authority. (Cite the specific authority for the INSCOM to engage in this project. Indicate date of approval, and if not yet approved, indicate specific approval authority needed for this project. Identify any POC in approval authority's organization with whom coordination has been effected.

Section III

PROTOCOL PLAN

11. General approach.

a. (Outline expected accomplishments in sufficient detail to show a clear course of action).

b. (Include discussion of the technological validity of the proposed research procedures).

c. (List the chronological steps to be taken).

12. Project subjects. (Give as a minimum the information below).

a. Number of subjects. (Indicate the total number of subjects expected to complete the study).

b. Age range.

c. Sex.

d. Inclusion criteria. (State specific and detailed reasons for inclusion of subjects by class, or individually, as appropriate).

e. Diagnostic criteria for entry.

f. Evaluations before entry. (Include any physical or psychological examinations, medical history, etc., which is to be done on each subject before entry into the project).

g. Exclusion criteria. (Include a complete list detailing the subjects, diseases, medications, etc., which constitute the criteria for exclusion from the project).

h. Source of subjects. (Describe briefly where subjects will be obtained).

i. Subject identification. (Describe code system, if any, which will be used in the project).

j. Subject assessment. (Describe the methods used to assign or allocate the object of this research to particular subjects).

k. Risks and benefits. (Discuss the analysis of risks and benefits to subjects and to those conducting the research).

l. Minimization of risks. (Discuss the precautions to be taken to minimize or eliminate risks to subjects and those conducting the research).

m. Corrective actions. (Describe hypothesized adverse reactions and corrective actions expected to be taken if such adverse reactions occur).

n. Special equipment. (Describe any special medical or nursing care or equipment needed for subjects admitted to the project).

13. Project technologies.

a. (State the complete name and description of all technologies to be used, including procedures for their application).

b. (Identify the source of all technologies and related items, devices, etc. List all components and manufacturing and quality control plans/ procedures, where applicable).

c. (Identify the methodology for application, if different from procedures described above).

d. (State the schedule, administration and duration of each aspect of the project).

e. (Describe in detail accompanying devices amd their intended use. Identify whether these are classified as medical devices and whether the medical devices amendment to the Federal Food, Drug and Cosmetic Act applies).

f. (Discuss labeling to medical devices, where applicable).

14. Evaluations made during and following the project. (A project schematic may be included, or the items may be listed as indicated below. In either case, it is important to identify the person who will perform each evaluation).

a. Specimens to be collected.

(1) Schedule of collections.

(2) Evaluations to be made on specimens.

(3) Storage. (If applicable, state where and if special conditions are required.)

(4) Labeling and disposition.

(5) Laboratories performing evaluations.

(6) Special precautions.

b. Clinical/behavioral assessments. (Include how adverse effects are to be recorded).

c. Vital signs. (State when desired and the frequency).

d. Follow-up procedures.

e. Disposition of data. (State location and duration of storage. Include pertinent information regarding Privacy Act and AR 381-10 considerations, if applicable).

f. Methods used for data collection. (State critical measurements used as end points to characterize safety, efficacy or equivalency).

15. Departure from protocol for individual subjects.

a. When allowed. (Use flexible, but definite criteria. If none is to be allowed, so state).

b. Who will be notified. (Include both those regarding the individual subject, if appropriate, and those elsewhere within the INSCOM. Must notify at least the HTRB).

16. Adverse reactions. (Must correlate with paragraph 12m, above).

a. Definition of subject reactions.

b. Immediate reporting procedures.

c. Routine reporting procedures.

d. Potential post-project adverse reactions.

Section IV

ADMINISTRATION

17. Modification of protocol. (Describe the procedure to be followed to modify, terminate or extend the protocol).

18. Disposition of unused project material. (Give a statement pertaining to disposition of unused project material and devices, if applicable).

19. Publications and reports. (Describe use, including potential restrictions, of information and publications and reports arising from the project).

20. Funding. (Identify source of funds and any special or unusual funding implications).

21. Medical monitor. (State the name and telephone number of medical monitor, when applicable).

22. Protocol review. (Identify the human use committee or institutional review board which will provide initial, continued and annual review of this protocol).

(Signature) _____
(Name, rank and organization of person submitting protocol)

(Signature) _____
(Name, rank and organization of principal investigator)

(Signature) _____
(Name, rank and organization of approving official)

Attachments
A - Proposed Volunteer Agreement
B - Proposed Explanation Portion of the Volunteer Agreement
C - Review of Scientific and Human Research Issues (if applicable)
D - Biographic Sketch of principal and associate investigators

APPENDIX C

VOLUNTEER AGREEMENT

Part A

I, _____, having attained my eighteenth (18th) birthday, and otherwise having full capacity to consent, do hereby volunteer to participate in an investigation study entitled: _____

_____

_____, and under the direction of _____

_____.

The implications of my voluntary participation; the nature, duration and purpose, and the methods and means by which it is to be conducted; and the inconveniences and hazards to be expected have been thoroughly explained to me by _____, and are set forth in Part B of this Agreement, which I have signed. I have been given the opportunity to ask questions concerning this investigative study, and any such questions have been answered to my full and complete satisfaction.

I understand that I may at any time during the course of this investigative study revoke my consent, and withdraw from the study without prejudice; however, I may be required to undergo certain further examinations, if, in the opinion of competent authority, such examinations are necessary for my health or well being.

_____ _____

Signature Date

_____ _____

Witness's Signature Date

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APPENDIX D

VOLUNTEER AGREEMENT

Part B

Explanation Portion of the Volunteer Agreement

1. Project title. (The title of the project and the place where it is to be conducted).

2. Principal investigator. (Must agree with the protocol).

3. Discussion. (A statement that the study involves research. An explanation of the purpose of the study and the expected duration of the subject's participation. A description of the procedures to be followed. An identification of any experimental procedures. A statement giving information about prior, similar, or related studies that provide the rationale for this project).

4. Risks or discomforts. (A description of any reasonably foreseeable risks or discomforts to the subject).

5. Benefits. (A description of any benefits to the subject or to others that may reasonably be expected from the study).

6. Alternative procedures. (A disclosure of proper alternative procedures or courses of treatment, if applicable, that might be advantageous to the subject).

7. Confidentiality of records. (A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Also, if more than a minimal risk is involved, a statement that authorities outside the US may inspect the records).

8. Subject's rights. (An explanation of whom to contact for answers to pertinent questions about the study and the subject's rights and whom to contact in the event of study-related injury to the subject).

9. Voluntary participation. (A statement that —

a. Participation is voluntary.

b. Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

c. The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled).

10. Compensation and medical treatment. (For a study involving more than minimal risk, an explanation as to whether any compensation and medical treatment

are available if injury occurs and, if so, what they consist of, or where further information may be obtained).

11. Additional comments. (When appropriate, one or more of the elements of information below will also be given to each subject.

a. A statement that a certain treatment or procedure may involve risks to the subject - or to the embryo or fetus if the subject is or may become pregnant - that are currently unforeseeable.

b. The anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the study.

d. The consequences of a subject's decision to withdraw from the study and procedures for the orderly end of the subject's participation.

e. A statement that new findings developed during the course of the study which could affect the subject's willingness to continue will be given to the subject.

f. The approximate number of subjects involved in the study.

g. The precautions to be observed by the subject before and after the study.)

STATEMENT OF CONSENT
INSCOM CENTER LANE PROJECT PARTICIPANT

IAGPA-F-SD Date:

1. (S/CL-4/NOFORN) I,_____ voluntarily accept assignment to the INSCOM CENTER LANE PROJECT (ICLP) and fully understand that:

a. (U) Army General Counsel has determined that ICLP constitutes experimentation on human subjects. As required by Procedure 13 of DoD Directive 5240.1-R, approval for project activities has been granted by Secretary of the Army.

b. (S/CL-3/NOFORN) The aim of ICLP is to develop highly skilled personnel who are capable of conducting professional level intelligence/counterintelligence operations through use of psychoenergetic methodology. Development of ICLP personnel will be accomplished with special training based on mission requirements.

c. (U) Assignments in ICLP are governed by the sensitivity and degree of expertise required for the position. I will be assigned in accordance with my capabilities and experience, regardless of my rank or previous position. Due to the nature of training involved, the duration of my participation is indefinite. Records of my involvement will be available to project personnel, but otherwise protected under project security measures.

d. (U) The primary consideration in any career development or assignment action will be ICLP mission and operational requirements. I understand that exemption, interruption, or delay in normal career development patterns--such as branch schooling and assignment opportunities--may prejudice future promotion and assignment potential. I have been assured, however, that every effort will be made to preclude the adverse effects listed above on my career.

2. (S/CL-3/NOFORN) PSYCHOENERGETICS (PE) include various processes by which individuals psychically interact with objects, locations, and organisms.

a. (U) There is no demonstrated risk of permanent or temporary injury (including physical, psychological and/or damage to participants' reputation) to project personnel beyond risks to which they would ordinarily be exposed in their daily lives.

b. (U) I may temporarily choose not to perform PE at specific times, or permanently discontinue participation without prejudicial effect.

WARNING NOTICE:
CENTER LANE SPECIAL ACCESS PROGRAM
RESTRICT DISSEMINATION TO THOSE WITH VERIFIED ACCESS
CATEGORY CL-4
NOT RELEASEABLE TO FOREIGN NATIONALS

CLASSIFIED BY: CDR, INSCOM
DECL: OADR

Incl 5

APPENDIX B

US ARMY
INTELLIGENCE AND SECURITY COMMAND
CENTER LANE TRAINING AND APPLICATIONS PROCEDURES

Psychological Test Descriptions

APPENDIX B

Psychological Test Descriptions

1. The Minnesota Multiphasic Personality Inventory (MMPI): Developed by S. R. Hathaway, Ph.D., and J. C. McKinley, M.D., The Psychological Corporation. The MMPI is designed to provide an objective assessment of some of the major personality characteristics that affect personal and social adjustment. The point of view determining the importance of a trait in this case is that of the clinical or personnel worker who wishes to assay those traits that are commonly characteristic of disabling psychological abnormality. The carefully constructed and cross-validated scales provide a means for measuring the personality status of literate adolescents and adults together with a basis for evaluating the acceptability and dependability of each test record. Nine scales were originally developed for clinical use of the inventory and were named for the abnormal conditions on which their construction was based. The scales were not expected to measure pure traits nor to represent discrete etiological or prognostic entities. Since they have been shown to have meaning within the normal range of behavior, these scales are now commonly referred to by their abbreviations--Hs (hypochondriasis), D (depression), Hy (Hysteria), Pd (psychopathic deviate), Mf (masculinity-femininity), Pa (paranoia), Pt (psychasthenia), Sc (schizophrenia), and Ma (hypomania)--or by their code numbers to avoid possibly misleading connotations. Many other scales have subsequently been developed from the same items; Si (social introversion) is one that is commonly scored. There are also three validating scales: L (lie), F (validity), and K (correction).

2. Gordon Personal Profile - Inventory (GPI): Developed by Leonard V. Gordon, Ph.D., The Psychological Corporation. The GPI is companion instrument to the Gordon Personal Profile (GPP). It measures four additional traits, namely Cautiousness (C), Original Thinking (O), Personal Relations (P), and Vigor (V). The two instruments used together provide an economical coverage of eight important factors in the personality domain. Both have been found to be appropriate for use with high school, college, industrial, and general adult groups.

3. Fundamental Interpersonal Relations Orientation - Behavior (FIRO - B): Developed by Will Schutz, Ph.D., Consulting Psychologists Press, Inc. The fundamental interpersonal dimensions of the FIRO Theory are; Inclusion (I), Control (C), and Affection (A) and are defined behaviorally as follows: I - The interpersonal need for inclusion is the need to establish

and maintain a satisfactory relationship with people with respect to interaction and association (both positive or negative). C - The interpersonal need for control is the need to establish and maintain a satisfactory relationship with people with respect to control and power. A - The interpersonal need for affection is the need to establish and maintain a satisfactory relationship with others with respect to love and affection.

4. California Psychological Inventory (CPI): Developed by Harrison G. Gough, Ph.D., Consulting Psychologists Press, Inc. The CPI is intended primarily for use with "normal" (non-psychiatrically disturbed) subjects. Its scales are addressed to personality characteristics important for social living and social interaction, i.e., to variables that are woven into the fabric of everyday life. "Folk concepts" such as these are hypothesized to be relevant to the prediction and understanding of interpersonal behavior in any setting, culture, or circumstance. Thus, although the inventory has been found to have special utility in work with particular kinds of problems, e.g., delinquent and asocial behavior, it can also provide information of value in regard to educational, vocational, familial, and many other issues.

5. Edwards Personal Preference Schedule (EPPS): Developed by Allen L. Edwards, Ph.D., University of Washington. The EPPS was designed primarily as an instrument for research and counseling purposes, to provide quick and convenient measures of a number of relatively independent normal personality variables. The statements in the EPPS and the variables that these statements purport to measure have their origin in a list of manifest needs presented by H. A. Murray and other noted psychologists. The names that have been assigned to the variables are those used by Murray. These 15 measurable personality variables are; achievement (ach), deference (def), order (ord), exhibition (exh), autonomy (aut), affiliation (aff), intraception (int), succorance (suc), dominance (dom), abasement (aba), nurturance (nur), change (chg), endurance (end), heterosexuality (het), and aggression (agg). In addition to the above 15 personality variables, the EPPS provides a measure of test consistency and a measure of profile stability.

6. Personal Orientation Inventory (POI): Developed by Everett L. Shostrom, Ph.D., Educational and Industrial Testing Service, San Diego, California. The profile on the POI shows the degree to which the subject's attitudes and values compare with those of self-actualizing people. A self-actualizing person is one who is more fully functioning and who lives a more enriched life than does the average person. Such a person is developing and utilizing his unique talents to the fullest extent.

TAB

DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
ARLINGTON HALL STATION
ARLINGTON, VIRGINIA 22212

REPLY TO
ATTENTION OF

IACG

MEMORANDUM OF AGREEMENT
BETWEEN
USA INTELLIGENCE AND SECURITY COMMAND AND THE DEFENSE INTELLIGENCE AGENCY

SUBJECT: Transfer of the INSCOM CENTER LANE Project to DIA (S/CL-2/NOFORN)

1. (S/CL-2/NOFORN) PURPOSE. This Memorandum of Agreement is intended to clarify the elements necessary for an effective transfer of the US Army Intelligence and Security Command (USAINSCOM) psychoenergetic intelligence collection capability to the Defense Intelligence Agency (DIA). This course of action is based on an agreement by DIA to accept the INSCOM CENTER LANE Project (ICLP) as a "package-deal" without a loss of any INSCOM personnel spaces. It is intended that the transfer will take place with minimum disruption to operations and training.

2. (U) REFERENCES.

a. (U) Memorandum, IACG, INSCOM, dtd 17 July 1984; subject: INSCOM CENTER LANE Project (U) (TAB A).

b. (U) Memorandum, DAMI-ISH, OACSI, dtd 1 August 1984; subject: CENTER LANE (U)--ACTION MEMORANDUM (U) (TAB B).

c. (U) Ltr, DAMI-ISH, OACSI, dtd 10 September 1984, subject: INSCOM CENTER LANE Project (TAB C).

d. (S/NOFORN) Memorandum of Agreement, DIA, dtd 17 August 1984, subject: "Operating rationale and terms of agreement for the participants in DoD psychoenergetics activities" (TAB D).

WARNING NOTICE: CENTER LANE SPECIAL ACCESS PROGRAM
RESTRICT DISSEMINATION TO THOSE WITH VERIFIED ACCESS
TO CATEGORY THREE (3)

SENSITIVE INTELLIGENCE SOURCES AND METHODS INVOLVED
NOT RELEASABLE TO FOREIGN NATIONALS

CLASSIFIED BY: CDR, INSCOM
DECLASSIFY ON: OADR

COPY_____OF_____COPIES

IACG
SUBJECT: Transfer of the INSCOM CENTER LANE Project to DIA (S/CL-2/NOFORN)

3. (S/CL-2/NOFORN) BACKGROUND. USAINSCOM has invested considerable effort since 1977 in developing psychoenergetic operational methods. Intelligence consumers in the US Army, US Air Force, DIA, NSA, CIA, and NSC have all tasked this methodology to augment other intelligence systems. These agencies have recognized the value and potential of the intelligence application of psychoenergetics; it is likely they will continue to task the system. The transfer of ICLP capability to DIA must be done in such a way as to maintain continuity and momentum of effort, as well as the state-of-the-art expertise exclusive to this time-proven, highly respected activity.

4. (S/CL-2/NOFORN) SCOPE. The effective transfer of ICLP to DIA requires the cooperation of INSCOM, DA (ACSI), and DIA.

5. (S/CL-3/NOFORN)) AGREEMENTS, SUPPORT, AND RESOURCES REQUIREMENTS. The "package deal" concept has been agreed to in principle by all parties involved. This concept has as its intent the transfer of all personnel, documents, equipment, and office space from INSCOM to DIA. The transfer of ICLP personnel to DIA will not involve the transfer of any INSCOM spaces. ICLP has been an active intelligence collection unit since 1978. It is intended that the unit will remain an operational element under the direct OPCON of the Assistant Vice Director for Scientific and Technical Intelligence (DT), DIA.

a. (S/CL-2/NOFORN) Personnel. All personnel assigned to INSCOM and working on ICLP will be encouraged to PCS to DIA for assignment to the DIA element that will perform the psychoenergetic training and collection mission. (Operational participation with CENTER LANE is strictly voluntary and falls under the guidelines of DoD directive 5240.1-R, AR 381-10, and Code of Federal Regulation, Title 45, part 46.)

b. (S/CL-2/NOFORN) Documents. All documents maintained by ICLP will be transferred to, and become the property and responsibility of, DIA. INSCOM will be permitted to retain access to command and control and historical ICLP documents.

c. (S/CL-2/NOFORN) Equipment. All ICLP equipment, rental agreements, and on hand supplies will be transferred to DIA. ICLP automatic data processing equipment and automobiles will remain with INSCOM.

d. (S/CL-2/NOFORN) Office Space. The affected agencies have agreed that the best course of action would be to continue to use the ICLP facilities at Ft. Meade, MD, which consists of two buildings, T-2560 and T-2561. Use of the Ft. Meade facility will provide the least amount of turmoil for the personnel involved,

permit continued operations and training with the least amount of disruption, and permit the best use of these buildings, which over the years have been modified to support this unique activity. Coordination with post authorities must be initiated to assign buildings T-2560 and T-2561 to DIA.

6. (U) RESPONSIBILITIES. USAINSCOM ICLP Project Manager will:

a. (S/CL-2/NOFORN) Function as INSCOM POC for transfer of ICLP to DIA.

b. (S/NOFORN) Coordinate for use or transfer of present ICLP physical facilities (bldgs. T-2560 and T-2561).

c. (S/CL-2/NOFORN) Coordinate transfer of ICLP equipment, contracts and rental agreements from INSCOM to DIA.

d. (S/CL-2/NOFORN) Coordinate the transfer of all ICLP personnel to DIA. Counsel all ICLP personnel concerning the transfer and insure ICLP personnel are aware that they will be performing operational remote viewing at DIA.

e. (S/CL-2/NOFORN) Coordinate for transfer of all relevant documents maintained by ICLP to DIA.

7. (S/CL-2/NOFORN) EFFECTIVE DATE. ICLP is scheduled to cease operations on or about 30 September 1984, at which time it will be available for transfer to DIA. It is expected that the transfer will be completed by 31 December 1984. Until completion of the transfer process ICLP will remain in its entirety within USAINSCOM.

HARRY E. SOYSTER
Major General, USA
Commanding

JAMES A. WILLIAMS
Lieutenant General, USA
Director

TAB

DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
ARLINGTON HALL STATION
ARLINGTON, VIRGINIA 22212

REPLY TO ATTENTION OF

12 FEB 1985

IACG

SUBJECT: Memorandum of Agreement, Transfer of INSCOM CENTER LANE Project (ICLP) to DIA (S/NOFORN)

HQDA
ATTN: DAMI-ZA
Washington, D.C. 20310-1001

1. (S/NOFORN) Reference: Letter, INSCOM, IAGPA-F-SD, 21 December 1984, subject: Transfer of CENTER LANE to DIA (S/CL-2/NOFORN) (Incl 1)

2. (S/NOFORN) Attached is the proposed INSCOM/DIA Memorandum of Agreement for the pending assumption of operational control of ICLP by the Defense Intelligence Agency.

3. (U) Request your review of attached MOA.

4. (U) Upon your approval, the MOA will be transmitted to DIA for their review and approval. Anticipated effective date for attachment of ICLP to DIA is 15 February 1985.

2 Incl
as

HARRY E. SOYSTER
Major General, USA
Commanding

CLASSIFIED BY: CG, INSCOM
DECLAS: OADR

SECRET

DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
ARLINGTON HALL STATION
ARLINGTON, VIRGINIA 22212

REPLY TO ATTENTION OF

IAGPA-F-SD

21 December 1984

SUBJECT: Transfer of CENTER LANE to DIA (S/CL-2/NOFORN)

HODA
ATTN: DAMI-ZA
Washington, D. C. 20310-1001

1. (U) DAMI-ISH Letter, 4 October 1984, subject: Memorandum of Agreement. (Incl 1)

2. (S/CL-3/NOFORN) Discussions with Defense Intelligence Agency (DIA) management now indicate that DIA will not be able to accept the transfer of INSCOM CENTER LANE Project (ICLP) assets until FY 1986. This is a result both of present Congressional restrictions on use of NFIP funding for psychoenergetic intelligence collection activities and a severe shortage of non-NFIP resources at DIA. DIA has requested operational control (OPCON) of ICLP as an interim measure, and has agreed to accept all command and control responsibility and liability for ICLP until such a time as Congress approves use of NFIP funds for psychoenergetic-related activities (expected no later than the first quarter of FY 86).

3. (S/CL-2/NOFORN) Based on the above, CG, USAINSCOM, has determined that the best course of action to permit the continued use of ICLP technology is to place the Project under DIA's OPCON. The target date for the action is 31 January 1985, which allows necessary time to accomplish preparation and staffing of a new

WARNING NOTICE: CENTER LANE
RESTRICTED DISSEMINATION
CONTROLLED ACCESS

THREE (3)

SENSITIVE INTELLIGENCE

1 2

Incl 1

SECRET

IAGPA-F-SD 21 December 1984
SUBJECT: Transfer of CENTER LANE to DIA (S/CL-2/NOFORN)

Memorandum of Agreement delineating the responsibilities of both parties. The period of the OPCON will not exceed one calendar year.

4. (S/CL-3/NOFORN) DIA has agreed to officially notify Congress of their assumption of responsibility for CENTER LANE.

5. (S/CL-2/NOFORN) The MOA will be forwarded to your office prior to submissi to DIA. Additionally, in a separate action, CENTER LANE will be disestablished as a Department of the Army Special Access Program (SAP). ACSI will be notified when this is fully accomplished.

HARRY E. SOYSTER
Major General, USA
Commanding

1 Incl
as

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT CHIEF OF STAFF FOR INTELLIGENCE
WASHINGTON, DC 20310

REPLY TO
ATTENTION OF

DAMI-ISH

4 OCT 1984

SUBJECT: Memorandum of Agreement (U)

Commander
USA Intelligence and Security Command
Arlington Hall Station
Arlington, VA 22212

1. (S/CL-2/NOFORN) Reference memorandum, INSCOM, IAGC, 26 Sep 84, subject: Memorandum of Agreement, Transfer of INSCOM CENTER LANE Project (ICLP) to DIA (S/CL-2/NOFORN).

2. (U) Reference proposed Memorandum of Agreement (MOA) is approved.

3. (S/CL-2/NOFORN) Request you consider the inclusion of some detail on the procedure to be followed in transferring personnel to DIA. INSCOM may detail the individuals involved for up to one year to allow time for DIA to identify spaces. Once such spaces are available, the detailed personnel may be given a Permanent Change of Station. If DIA desires a change in authorized strength to allow for immediate PCS reassignment, they may apply for it through JCS. OACSI, DA will support such a change in status if the subject becomes an issue.

WILLIAM E. ODOM
Lieutenant General, USA
ACofS for Intelligence

Classified by Cdr, INSCOM
Declassify on: OADR

CENTER LANE

TAB

Approved For Release 2004/07/09 : CIA-RDP96-00788R001500090010-7

DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
ARLINGTON HALL STATION
ARLINGTON, VIRGINIA 22212

REPLY TO
ATTENTION OF

IACG

SUBJECT: Deactivation of INSCOM CENTER LANE Project (ICLP) as a Special Access Program (SAP) (U)

HQDA
ATTN: DAMI-ZA
Washington, D.C. 20310-1001

1. (S/NOFORN) This letter serves to notify you of the deactivation of the INSCOM CENTER LANE Project, the attachment OPCON of CENTER LANE assets and resources to the Defense Intelligence Agency, and the retirement of CENTER LANE as an active project nickname, effective as of the date of this letter.

2. (U) Request that the necessary actions be taken to officially discontinue CENTER LANE as a Secretary of the Army designated Special Access Program.

HARRY E. SOYSTER
Major General, USA
Commanding

CLASSIFIED BY: CG, INSCOM
DECLAS: OADR

NOT RELEASABLE TO FOREIGN NATIONALS